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September 6, 2001

Dr. Michael Shelby, Director
Center for the Evaluation of Risks to Human Reproduction
National Institute of Environmental Health Sciences
79 T.W. Alexander Drive, Building 4401, Room 103
P.O. Box 12233, MD EC-32
Research Triangle Park, NC 27709

TRANSMITTED ELECTRONICALLY TO: shelby@niehs.nih.gov

Dear Dr. Shelby:

These comments are submitted on behalf of People for the Ethical Treatment of Animals (PETA) and our over 750,000 members in response to a *Federal Register* notice of July 16, 2001, soliciting public comment on the draft expert report on methanol released by the National Toxicology Program's (NTP) Center for the Evaluation of Risks to Human Reproduction's (CERHR).

It is impossible to tell from the draft that is available from the NTP web site, http://cerhr.niehs.nih.gov/news/methanol_report.PDF, whether or not the CERHR's conclusion is that insufficient animal data exist on the potential reproductive and developmental risks of methanol to humans. The report is not presented in a "user-friendly" manner and omits the preface and conclusions of the draft expert report, including such critical information as the data needs section. As a result, the public cannot fully review the conclusions of the expert panel in order to gain valuable insight into the panel's priorities when formulating its conclusions.

We sincerely hope that the U.S government does not believe that additional animal tests should be conducted on methanol. The CERHR draft report itself details the abundant existing data on the reproductive and developmental toxicity of methanol to rats and non-human primates. The test plan for methanol, submitted by the American Methanol Institute Testing Group, also provides extensive data on this substance—including reproductive and developmental data—and calls for no further testing under the Environmental Protection Agency's high production volume chemical testing program.

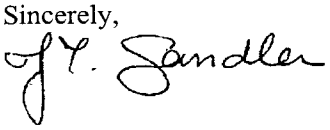
A wealth of existing epidemiological and toxicological data provides more than adequate information to understand the potential health implications of methanol exposure. Information on the extensive natural, food-additive-related (e.g., aspartamine), and industrial human exposure to methanol provide a rich set of existing cohorts by which to evaluate the potential reproductive effects of methanol on human populations. Further, the fundamental biochemical basis of methanol metabolism and toxicity—in which methanol toxicity is related to the rate of formate metabolism—is well understood and

can provide additional data on the toxicity of this ubiquitous compound. Any further testing of methanol on animals would be pointless and cruel.

Finally, we would like to notify the CERHR of our intention to submit more extensive public comments jointly with the Physicians Committee for Responsible Medicine at the Methanol Expert Panel Meeting scheduled for October 15-17, 2001, in Alexandria, Virginia.

Thank you for your attention to these comments.

Sincerely,



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Federal Agency Liaison
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